PROPOSED ORDER OF DEPARTMENT OF HEALTH SERVICES TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services (the "department") proposes an order to repeal DHS 144.03 (3m) (a) and (b), and DHS Table 144.03-A (Notes 4 & 5); to amend DHS 144.01 (2), DHS 144.02 (9) and (10), DHS 144.03 (1) and (2) (a) and (d), DHS 144.03 (4) to (6) and (10) (a), DHS 144.04 and 144.05, and DHS 144.07 (Title), (1), (1m) and (3), DHS 144.07 (4) (b), (5), (6), (7), (9), and (10), DHS 144.08 (1) and (3), DHS 144.09 (1) (a); to repeal and recreate DHS 144.01 (1), DHS 144.02 (1), DHS 144.02 (12), DHS 144.03 (2) (f), DHS 144.07 (4) (a), DHS 144.09 (1) (c) (Note), and DHS Table 144.03-A and (Notes 1 to 3); and to create DHS 144.02 (05), DHS 144.02 (4g), DHS 144.02 (7m), DHS 144.03 (2) (f) (Note), DHS 144.03 (3), relating to immunization of students.

RULE SUMMARY

Statutes interpreted

Section 252.04, Stats.

Statutory authority

Sections 252.04 and 227.11 (2) (a), Stats.

Explanation of agency authority

The Legislature directed the department in s. 252.04 (1), Stats., to carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus.

Related statute or rule

Chapters DHS 145 and 146 Chapter 250, Stats.

Plain language analysis

The department is required to carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus. Minimum immunization requirements for entry into Wisconsin schools and child care centers are established in ch. DHS 144. The department proposes to make the following revisions to the rule chapter:

1. Varicella (chicken pox) and meningococcal disease are identified by the department as vaccine-preventable diseases. However, a substantial outbreak of these diseases is not currently defined in ch. DHS 144. The department proposes to amend the definition of a "substantial outbreak" to include Varicella (chicken pox) and meningococcal disease, and to ensure consistency with CDC recommendations.

- 2. In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high-transmission settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the *Manual for the Surveillance of Vaccine-Preventable Diseases*, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a "substantial outbreak" of mumps to be consistent with the CDC *Manual for the Surveillance of Vaccine-Preventable Diseases*.
- 3. The department is proposing to move the current recommendation for Tdap from 6^{th} grade to 7^{th} grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6^{th} grade). This will reduce the number of children who enter 6^{th} grade and are not vaccinated for Tdap, as some clinicians choose to wait until they are 11 years of age to vaccinate.
- 4. *Neisseria meningitidis* is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The meningococcal vaccine is recommended by the Wisconsin Chapter of the American Academy of Pediatrics and the Wisconsin Academy of Family Physicians to reduce the incidence of bacterial meningitis and sepsis. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The department proposes to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are administered at the same visit and the same grade level. The department also proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations. This will help to ensure students are fully vaccinated prior to leaving school.
- 5. Under the current rule, a parent or adult student may report a history of varicella disease as an acceptable exception to varicella vaccination. Recent studies have demonstrated that there is a high incidence of unvaccinated children who report a positive history of varicella that are not immune. The department proposes to allow the exception only when a history of varicella disease has been reported by a health care provider.
- 6. Chapter DHS 144 currently includes provisions relating to the 2008-2009 phase-in of Tdap and Varicella Vaccine coverage. The department proposes to eliminate these provisions because phase-ins are completed.
- 7. Curently, schools must only report compliance with program requirements and key indicators of vaccine-preventable disease and outbreaks to local health departments. The department proposes to add the state as a recipient of these reports which would be congruent with the current day care reporting requirements. This will improve the availability of important information and improve the department's reporting to the legislature, under s. 252.04 (11), Stats..

8. Chapter DHS 144 has not been substantially revised since 1981. The department proposes to update, correct, or clarify any outdated provisions in order to reflect current definitions, standards, and best practices.

There are no reasonable alternative to the proposed rulemaking. The department is required by s. 252.04 (1), Stats., to maintain a statewide immunization program.

Summary of, and comparison with, existing or proposed federal regulations

There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rules.

Comparison with rules in adjacent states

Similar to the proposed rule, Illinois, Iowa, Michigan, and Minnesota all require at least one dose of meningococcal conjugate vaccine at either 6th or 7th grade. All states but Michigan require a booster dose either at the appropriate age of 16-18 years or grade 12, as is proposed in the proposed rule.

Similar to the proposed rule, adjacent states all require Tdap vaccine for students entering 7th grade, require a health care provider's documentation of varicella disease instead of parental reporting, and refer to CSTE case definitions and CDC guidance and recommendations in regards to disease outbreak definitions.

These states all have similar reporting requirements of vaccine preventable diseases.

Illinois:

The Illinois Department of Public Health outlines school and child care immunization requirements in 77 Ill. Admin. Code 665. Beginning with the school year 2015-2016, a student entering the 6th grade is required to have received one dose of meningococcal conjugate vaccine on or after their eleventh birthday. Students who do not meet the age requirement are monitored by the school. A student entering the 12th grade is required to have a second dose after their sixteenth birthday. If the first dose is administered when the student is sixteen years of age or older, only one dose is required.

The Tdap vaccine is required for students entering 7^{th} through 12^{th} grade.

Proof of prior varicella disease must be verified with the date of illness signed by a physician, a health care provider's interpretation that a parent's or legal guardian's description of varicella disease history is indicative of past infection, or laboratory evidence of varicella immunity. A health care provider is defined as a physician, child care or school health professional, or health official.

The Illinois Department of Public Health 77 Ill. Admin. Code 690 outlines mandated reporters, such as health care providers, hospitals, and schools, to report suspected or confirmed cases of vaccine-preventable diseases which include the same diseases as outlined in the proposed rule.

http://www.ilga.gov/commission/jcar/admincode/077/07700665sections.html.

Iowa:

Iowa Code, Chapter 139a.8(6) and Iowa Administrative Code, 641-7.7(139) outline the immunization requirements for student attending school and licensed child care centers. Beginning with the 2017-2018 school year, a student entering the 7th grade is required to have one dose of meningococcal (A, C, W, Y) vaccine. A student entering the 12th grade is required to have two doses, or one dose if the first dose is received at sixteen years of age or older.

The Tdap vaccine is required for students in 7th grade and above.

While not addressed in the codes, per the certificate of immunization document, varicella disease must be certified by a physician, physician assistant, nurse, or certified medical assistant.

Reporting of vaccine preventable diseases is required by Iowa Administrative Code 641-1 and includes the same diseases as outlined in the proposed rule.

https://www.legis.iowa.gov/docs/code/139A.8.pdf. https://www.legis.iowa.gov/docs/ACO/chapter/641.7.pdf.

Michigan:

School and child care immunization requirements are set forth in MCL 333.9205, 333.9208, 333.9227, and 380.1177. Since the 2014-2015 school year, a student entering the 7th grade has been required to have one dose of meningococcal (A, C, W, Y) vaccine. There is no requirement for a second dose.

The Tdap vaccine is required for students at eleven years of age or older upon entry into the 7th grade or higher.

Michigan requires documentation of either history of varicella disease or current lab immunity.

MCL 333.5111(1)b contains the requirements for reporting communicable diseases and includes the same diseases as the proposed rule.

http://www.legislature.mi.gov/(S(nts2urh1szbck2ti1ksr4sn4))/mileg.aspx?page=getobject&objectmame=mcl-333-9205.

Minnesota:

Minnesota's Administrative Rule Chapter 4604 outlines the school and child care immunization requirements. Since the 2014-2015 school year, a student entering the 7th grade has been required to have one dose of meningococcal vaccine (A, C, W, Y). A second dose is required at age sixteen years.

The Tdap vaccine is required for students entering the 7th grade.

Documentation of past varicella disease must include the signature of a provider and the date of the student's varicella illness, the signature of a provider and a statement that a parent's or legal

guardian's description of the varicella disease history is indicative of past varicella infection, or the signature of a provider or a representative of a public clinic, and must include laboratory evidence of the child's varicella immunity. A provider is defined as a licensed physician, registered physician assistant, or advanced practice registered nurse.

Minnesota's communicable disease rule and requirements are in Chapter 4605 and include the same vaccine preventable diseases as in the proposed rule.

https://www.revisor.mn.gov/rules/?id=4604.

Summary of factual data and analytical methodologies

The department relied on the following sources to draft the proposed rule:

- A. Heymann DL, ed. *Control of Communicable Diseases Manual*. 20th ed. Washington, DC: American Public Health Association, 2015.
- B. Pickering LK, ed. *Red Book: 2015 Report of the Committee on Infectious Diseases.* 30th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2015.
- C. Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.
- D. Centers for Disease Control and Prevention. Manual for the Surveillance of Vaccine-Preventable Diseases Measles website: https://www.cdc.gov/vaccines/pubs/surv-manual/index.html.
- E. Council of State and Territorial Epidemiologists. Infectious Disease: Vaccine-Preventable Diseases (VPD) website: http://www.cste.org/members/group.aspx?id=87594.

The department formed an Advisory Committee consisting of representatives from the Wisconsin Department of Public Instruction, Wisconsin Chapter of the American Academy of Pediatrics, Wisconsin Department of Health Services Medicaid Program, Wisconsin Association of Local Health Departments and Boards, Wisconsin Academy of Family Physicians, Wisconsin Association of School Nurses, Wisconsin Medical Society, and Pharmacy Society of Wisconsin. Proposed rule revision language was drafted based on the recommendations of this committee.

Analysis and supporting documents used to determine effect on small business TBD

Effect on small business TBD

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Statement on quality of agency data

The data sources referenced and used to draft the rules and analyses are accurate, reliable, and objective and are discussed in the "Summary of factual data and analytical methodologies."

Place where comments are to be submitted and deadline for submission

Comments on the proposed rules may be submitted by accessing the department's rules site, at https://www.dhs.wisconsin.gov/rules/permanent.htm. Once a public hearing has been scheduled, additional commenting will be enabled through the Wisconsin State Legislature's site, at http://docs.legis.wisconsin.gov/code. The notice of pubic hearing and the deadline for submitting comments will be published both to the department's rules site, an in the Administrative Register, at https://docs.legis.wisconsin.gov/code/register.

RULE TEXT

SECTION 1. DHS 144.01 (1) is repealed and recreated to read:

DHS 144.01 (1) This rule implements s. 252.04, Stats., which requires the department to carry out a statewide immunization program to eliminate, immunize and protect against certain diseases specified in statute or by department rule. This chapter addresses immunization requirements for vaccine-preventable diseases, by students admitted into schools or children admitted into child care settings.

SECTION 2. DHS 144.01 (2) is amended to read:

DHS 144.01 (2) The emphasis placed in this chapter on meeting minimum immunization requirements upon entry to Wisconsin schools at any grade level or to a day child care center complements efforts by the department to promote early immunization of infants and preschoolers according to accepted immunization schedules.

SECTION 3. DHS 144.02 (05) is created to read:

"Advanced practice nurse prescriber" has the meaning given in s. N. 8.02 (2).

SECTION 4. DHS 144.02 (1) is repealed and recreated to read:

DHS 144.02 (1) "Child care center" has the meaning given in s. 49.136 (1) (ad), Stats.

SECTION 5. DHS 144.02 (4g) is created to read:

DHS 144.02 (4g) "Mening" means a meningococcal vaccine containing, at a minimum, serogroups A, C, W, and Y.

SECTION 6. DHS 144.02 (7m) is created to read:

DHS 144.02 (7m) "Physician assistant" has the meaning given in s. 448.01 (6), Stats.

SECTION 7. DHS 144.02 (9) and (10) are amended to read:

DHS 144.02 (9)"School day" in reference to schools has the meaning prescribed in s. 115.01 (10), Stats. A school day for a day child care center is any day that the center is open and caring for children.

DHS 144.02 (10) "Student" means any individual enrolled in <u>or attending</u> a school or <u>day child</u> care center-or attending a school or <u>child</u> care center.

SECTION 8. DHS 144.02 (12) is repealed and recreated to read:

"Substantial outbreak" means occurrence of any of the following diseases at the threshold determined by the department and by using epidemiological factors such as time and place.

- 1. Measles.
- 2. Mumps.
- 3. Rubella.
- 4. Polio.
- 5. Pertussis.
- 6. Diphtheria.
- 7. Haemophilus influenzae type b.
- 8. Varicella.
- 9. Meningococcal disease.

SECTION 9. DHS 144.03 (1) and (2) (a) and (d) are amended to read:

DHS 144.03 (1) INDIVIDUALS INCLUDED. The minimum immunization requirements authorized by s. 252.04, Stats., apply to any student admitted to a Wisconsin elementary, middle, junior or senior high school or to a Wisconsin day child care center.

DHS 144.03 (2) (a) Table DHS 144.03-A as qualified by pars. (b) to (g) lists the number of doses of each required vaccine that each student in the 2008-09 2020-21 school year and following school years shall have received since birth for the age or grade of the student. These comprise the minimum immunizations required under s. 252.04 (2), Stats. They do not, however, represent all the recommended immunizations according to currently accepted immunization schedules.

DHS 144.03 (2) (d) For students in ungraded schools or students age 5 or older in <u>day child</u> care centers, the immunization requirements are those for the grade which would normally correspond to the individual's age. <u>Immunization Immunizations</u> against <u>measles</u>, <u>mumps</u>, and

rubella is MMR, Tdap, Var, and Heb B are also required for all students age 19 or older, as referenced for Grade 12 in Table DHS 144.03-A.

SECTION 10. DHS 144.03 (2) (f) is repealed and recreated to read:

DHS 144.03 (2) (f) Exceptions may be made in requirements for Var vaccine. Students who have a reliable history of varicella disease are not required to receive Var vaccine. A physician, physician assistant, or an advanced practice nurse prescriber must document a reliable history of varicella disease by indication on the department's student immunization form that the student has had varicella disease.

SECTION 11. DHS 144.03 (2) (f) (Note) is created to read:

Note: The student immunization record form (DHS Form 04020L) is available by accessing: https://www.dhs.wisconsin.gov/library/F-04020L.htm.

SECTION 12. DHS 144.03 (3) is repealed and recreated to read:

DHS 144.03 (3) MENING VACCINE IMPLEMENTATION. Beginning with the 2008-09 2020-21 school year, students entering grades 7 and 12 shall have received Tdap Mening vaccine in addition to the other required vaccines listed in Table DHS 144.03-A as qualified by sub. (2) (b) to (i).

SECTION 13. DHS 144.03 (3m) (a) and (b) are repealed.

SECTION 14. DHS 144.03 (4) to (6) and (10) (a) are amended to read:

DHS 144.03 (4) FIRST DEADLINE. Within 30 school days after having been admitted to a school or-day child care center, each student who has not filed a waiver form shall submit written evidence of having completed at least the first dose of each vaccine required for that student's age or grade, as outlined in Table DHS 144.03-A.

DHS 144.03 (5) SECOND DEADLINE. Within 90 school days after having been admitted to a school or day child care center, each student who has not filed a waiver form shall submit written evidence of having received the second dose of each vaccine required for that student's age or grade, as outlined in Table DHS 144.03-A.

DHS 144.03 (6) FINAL DEADLINE. Within 30 school days after having been admitted to a school or day child care center for the following school year, each student who has not filed a waiver form shall submit written evidence of having received the third and, if required, the fourth dose of both DTP/DTaP/DT/Td and polio vaccines and the final dose of Hep B in grades required under sub. (3) and, for students in day child care centers, the final dose of Hib vaccine, if a dose has not been received at or after 15 months of age.

DHS 144.03 (10) (a) Between vaccine providers and schools or-day child care centers. Vaccine providers shall disclose a student's immunization information, including the student's name, date

of birth and gender and the day, month, year and name of vaccine administered, to a school or day child care center upon written or verbal request from the school or day child care center. Written or verbal permission from a student or parent is not required to release this information to a school or day child care center.

SECTION 15. DHS 144.04 and 144.05 are amended to read:

DHS 144.04 Upon certification by a-licensed physician that an immunization required under s. 252.04, Stats., is or may be harmful to the health of a student, the requirements for that immunization shall be waived by the department. Written evidence of any required immunization which the student has previously received shall be submitted to the school or-day child care center with the waiver form.

DHS 144.05 Immunization requirements under s. 252.04, Stats., shall be waived by the department upon presentation of a signed statement by the parent of a minor student or by the adult student which declares an objection to immunization on religious or personal conviction grounds. Written evidence of any required immunization which the student has previously received shall be submitted to the school or day child care center with the waiver form.

SECTION 16. DHS 144.07 (Title), (1), (1m) and (3) are amended to read: DHS 144.07 (Title) Responsibilities of schools and day child care centers. DHS 144.07 (1) The responsibilities of schools under these rules shall be those of the local school board and the school administrator. The licensee for each day child care center shall be responsible for compliance with these rules. The school or day child care center shall assure compliance with s. 252.04 (2), Stats.

DHS 144.07 (1m) By the 15th school day after a child or adult is admitted to a school or day child care center and again by the 25th school day after a child or adult is admitted to a school or day child care center, the school or day child care center shall notify the adult student or the parent of any minor student who has not submitted either written evidence of immunization or a waiver form.

DHS 144.07 (3) If any minor student for whom a waiver form is not filed fails to comply with the immunization requirements described in s. DHS 144.03 by the date of admission to the school or-day child care center, the school or-day child care center-shall may, within 60 school days of that failure to comply, notify the district attorney in writing, with the notice to include the student's name and the name and address of the student's parent, and request the district attorney to seek a court order under s. 48.13 (13), Stats. The school or-day child care center-shall may keep the district attorney apprised of the subsequent compliance of a student initially reported to the district attorney.

SECTION 17. DHS 144.07 (4) (a) is repealed and recreated to read:

DHS 144.07 (4) (a) The school and the child care center shall report to both the local health department and the department the degree of compliance with s. 252.04, Stats., and this chapter by students in that school or child care center.

SECTION 18. DHS 144.07 (4) (b), (5), (6), (7), (9), and (10) are amended to read:

DHS 144.07 (4) (b) These reports shall be in a format prescribed by the department and shall be made by schools within 40 school days after the beginning of the term and by <u>day child</u> care centers at intervals prescribed by the department.

DHS 144.07 (5) The school and the <u>day child</u> care center shall maintain on file the immunization history for each student and any waiver form submitted. Immunization histories shall be updated with information supplied by the local health department, parents or private physicians.

DHS 144.07 (6) The school or day child care center shall maintain a current roster listing the name and immunization history of each student who does not meet all immunization requirements for that student's grade or age.

DHS 144.07 (7) The immunization record of any new student who transfers from one school or day child care center to another shall be forwarded to the new school or day child care center within 10 school days of the request for record transfer. The records of a day child care student shall be transferred to a school if requested by either the admitting school or the parent.

DHS 144.07 (9) If one of the diseases covered by s. 252.04 (2), Stats., or this chapter occurs in a student or staff member, the school or day child care center shall assist the local health department and the department in immediately identifying any unimmunized students, notifying their parents of the possible exposure and facilitating the disease control activities.

DHS 144.07 (10) If a substantial outbreak as defined in s. DHS 144.02 (12) occurs in a school or day child care center, or in the municipality in which a school or day child care center is located, the school or day child care center shall exclude students who have not received all required immunizations against the disease, including students in all grades who have not had 2 doses of measles vaccine when it is an outbreak of measles that is occurring, when ordered to do so by the department. The exclusion shall last until the student is immunized or until the department determines that the outbreak has subsided.

SECTION 19. DHS 144.08 (1) and (3) are amended to read:

DHS 144.08 (1) By mutual agreement, responsibility for making the needed immunizations available may be transferred from the local health department to a school or <u>day child</u> care center.

DHS 144.08 (3) The local health department shall assist the department in informing schools and day child care centers of the provisions of s. 252.04, Stats., and this chapter.

SECTION 20. DHS 144.09 (1) (a) is amended to read:

DHS 144.09 (1) (a) The department, in cooperation with local boards of health and health officers, local school boards and school and day child care center administrators and other

agencies, as appropriate, shall provide guidance to parents, physicians, schools and <u>day child</u> care centers and local health departments in understanding the minimum immunization requirements under s. 252.04, Stats., and this chapter, the reasons behind their establishment and the process for implementing them.

SECTION 21. DHS 144.09 (1) (c) (Note) is repealed and recreated to read:

DHS 144.09 (1) (c) (Note) Contact the Wisconsin Immunization Program at 608-267-9959 for copies of required reporting and waiver forms.

SECTION 22. DHS Table 144.03-A and (Notes 1 to 3) are repealed and recreated to read:

Table 144.03-A
Required for the 2020-21 School Year and
the Following School Years

	I						-		
Age/Grade	Required Immunizations (Number of Doses)								
5 months	2		2			2 Hep	2	2	
through 15	DTP/DTaP/D		Polio			В	Hib	PCV	
months	T								
16 months	3		2	1		2 Hep	3	3	
through 23	DTP/DTaP/D		Polio	MMR		В	Hib^2	PCV	
months	T								
2 years	4		3	1	1	3 Нер	3	3	
through 4	DTP/DTaP/D		Polio	MMR	Var	В	Hib^2	PCV	
years	T								
Kindergarten	4		4	2	2	3 Нер			
through grade	DTP/DTaP/D		Polio	MMR	Var	В			
5	T^1								
Grade 7	4	1	4	2	2	3 Hep			1 Mening
through grade	DTP/DTaP/D	Tdap	Polio	MMR	Var	В			
_11	T								
Grade 12	4	1	4	2	2	3 Нер			
	DTP/DTaP/D T	Tdap ²	Polio	MMR	Var ³	В			2 Mening ³

¹For kindergarten only, at least one dose to be received after 4 years of age unless medically contraindicated. A dose received 4 days or less before the fourth birthday is acceptable.

²At least one dose to be received after 12 months of age unless medically contraindicated. A dose received 4 days or less before the first birthday is acceptable.

³If the first dose is administered at age 11 through 15 years, a booster dose should be administered at age 16 through 18 years. If the first dose is administered at age 16 years or older, a booster dose is not needed.

SECTION 23. DHS Table 144.03-A (Notes 4 & 5) are repealed.

SECTION 24. EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2), Stats.

